Before the
FEDERAL COMMUNICATIONS COMMISSION
Washington, D.C. 20554

In the Matter of	)	
	)	
Promoting Expanded Opportunities for Radio Experimentation and Market Trials under Part 5 of the Commission's Rules and Streamlining Other Related Rules	)	EB Docket No. 10-236
	)	
2006 Biennial Review of Telecommunications Regulations—Part 2 Administered by the Office of Engineering and Technology (OET)	)	ET Docket No. 06-155
	)	

PETITION FOR RECONSIDERATION OF MEDTRONIC, INC.

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May 29, 2013

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Pursuant to Section 1.429 of the Commission's rules,[1] Medtronic, Inc. ("Medtronic") respectfully petitions the Federal Communications Commission (the "Commission") to reconsider two narrow aspects of its recent *Experimental Radio Service* ("ERS") *Report and Order* (the "*ERS Order").*[2]

I. INTRODUCTION AND SUMMARY

Medtronic recognizes and applauds the Commission's vision and hard work in crafting the *ERS Order*. In many areas, the *ERS Order* successfully realizes the Commission's intent and strikes the required balance between providing an environment where creativity can thrive while protecting incumbent spectrum users. However, Medtronic seeks reconsideration of two aspects of the new rules.

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1 47 C.F.R. § 1.429.

2 *Promoting Expanded Opportunities for Radio Experimentation and Market Trials under Part 5 of the Commission's Rules and Streamlining Other Related Rules*, Report and Order, 28 FCC Rcd 758 (2013) ("*ERS Order*"). Medtronic participated in the proceeding leading to the adoption of the *ERS Order*, filing comments in the proceeding.

First, Medtronic urges the Commission to extend the eligibility for medical testing licenses to all sponsors and sponsor-investigators, as defined by the Federal Food and Drug Administration's ("FDA's") rules, of clinical trials involving the testing and operation of new medical devices. The Commission established the medical testing license to meet the testing needs of the medical community and to allow entities doing medical research to conduct clinical trials. However, the Commission limited eligibility for the license to health care facilities, despite the fact that a variety of entities stand to benefit from the flexibility offered by the new license.[3] By barring a significant portion of the medical community involved in clinical trials from obtaining medical testing licenses, the *ERS Order* reflects a misunderstanding of the process of medical device development, arbitrarily imposes additional costs and burdens on entities that sponsor or conduct clinical trials but do not meet the Commission's narrow definition of "health care facility," and discourages the very innovation it seeks to encourage.

Second, as requested in its opening comments, Medtronic urges the Commission to clarify that cost reimbursement for clinical trials, as allowed by FDA regulations, does not constitute impermissible "marketing" under Section 2.803 or 2.805 of devices that have not yet been approved.[4] The requested clarification will ensure consistency between the two regulatory regimes, simplify manufacturers' compliance, and encourage medical device testing and innovation.

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[3] *See* 47 C.F.R. § 5.402(a). Section 95.1103(b) of the Commission's rules defines a health care facility to include "…hospitals and other establishments that offer services, facilities and beds for use beyond a 24 hour period in rendering medical treatment, and institutions and organizations regularly engaged in providing medical services through clinics, public health facilities, and similar establishments, including government entities and agencies such as Veterans Administration hospitals; except the term health care facility does not include an ambulance or other moving vehicle." 47 C.F.R. § 95.1103(b).

[4] 47 C.F.R. §§ 2.803, 2.805. *See also* Comments of Medtronic, Inc., ET Docket Nos. 10-236 and 06-155 at 5-6 (filed Mar. 10, 2011) ("Medtronic Comments").

II. THE COMMISSION SHOULD EXTEND THE ELIGIBILTY FOR MEDICAL TESTING LICENSES TO INCLUDE ALL SPONSORS AND SPONSOR-INVESTIGATORS OF CLINICAL TRIALS

In the *ERS Order*, the Commission recognized that its previous experimental rules were "not always nimble enough to account for the speed of today's technological development" and that its previous processes could "delay the introduction of new technologies into the marketplace" and "prevent the American public from expeditiously taking advantage of technological advances."[5] Unfortunately, by limiting the eligibility for medical testing licenses to health care facilities, the Commission's new experimental licensing framework threatens to do the same.

A variety of entities that do not meet the Commission's definition of "health care facility" require the flexibility offered by medical testing licenses to sponsor and conduct clinical trials and bring new medical technologies to consumers. An experimental license program that does not permit all sponsors and sponsor-investigators to engage in clinical trial testing in residential settings without seeking a separate experimental authorization or certification for a device in the latter stages of development is not aligned with FDA regulations, does not meet the needs of the medical community, and is considerably less valuable to the public. Moreover, by excluding a significant portion of sponsors and sponsor-investigators from eligibility for medical testing licenses, the Commission arbitrarily imposes additional costs and regulatory burdens on these entities and slows innovation and product development to the harm of consumers. Accordingly, the public interest requires that the Commission reconsider its decision in the *ERS Order* and extend the eligibility for medical testing licenses to all sponsors and sponsor-investigators of medical device clinical trials.

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[5] *ERS Order* at ¶ 20.

A. The Commission's New ERS Rules Are Not Aligned With FDA Regulations That Permit a Variety of Entities to Sponsor or Conduct Clinical Trial Testing

Unlike the Commission's new rules, the FDA's rules allow a variety of entities to engage in clinical trial testing of medical devices. The FDA classifies certain entities involved in medical device research as either "sponsors" or "sponsor-investigators" of clinical trials. Pursuant to Section 812.3(n), a sponsor of a clinical trial is:

> A person who initiates, but who does not actually conduct, the investigation, that is the investigational device is administered, dispensed, or used under the immediate direction of another individual. A person other than an individual that uses one or more of its own employees to conduct an investigation that it has initiated is a sponsor, not a sponsor-investigator, and the employees are investigators.[6]

Sponsors ultimately are responsible for the clinical trial.[7] The FDA holds the sponsor responsible for the planning, conduct, oversight, results, and compliance aspects of clinical trial testing. Moreover, the FDA's rules recognize that entities beyond health care facilities are capable of acting as sponsors and engaging in "the conduct of research on subjects or in the delivery of medical services to individuals as a primary activity…"[8]

A sponsor-investigator, on the other hand, is defined by Section 812.3(o) of the FDA's rules as:

> An individual who both initiates and actually conducts, alone or with others, an investigation that is, under whose immediate direction the investigational device is administered, dispensed, or used. The term does not include any person other

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6 21 C.F.R. § 812.3(n).

7 *See* 21 C.F.R. § 812.40. *See also* 21 C.F.R. Part 812, Subparts B and G.

8 The FDA defines an "institution" as "a person, other than an individual, who engages in the conduct of research on subjects or in the delivery of medical services to individuals as a primary activity or as an adjunct to providing residential or custodial care to humans. The term includes, for example, a hospital, retirement home, confinement facility, academic establishment, and device manufacturer. The term has the same meaning as 'facility' in section 520(g) of the act." 21 C.F.R. § 812.3(e).

> than an individual. The obligations of a sponsor-investigator under this part include those of an investigator and those of a sponsor.[9]

Under these rule sections, a wide-range of entities, including hospitals, health care facilities, and medical device manufacturers, among others, act as sponsors and sponsor-investigators of clinical trials and engage in real-world patient testing.[10] For example, ClinicalTrials.gov, a registry and results database of publicly and privately supported clinical studies, currently lists the Mayo Clinic as a sponsor of 925 clinical trials.[11] The same database lists Medtronic as a sponsor of 386 trials.[12] ClinicalTrials.gov also lists Boston Scientific, Biotronik, St. Jude Medical, and GE Healthcare as clinical trial sponsors.[13]

Importantly, many FDA-defined sponsors and sponsor-investigators engage in development testing and operation of new medical devices that use wireless telecommunications technology for therapeutic, monitoring, or diagnostic purposes that have not yet been submitted for equipment certification, and devices designed to meet the Commission's technical rules under Part 18 for non-communication uses of RF energy. They are intimately involved in all stages of the medical device development process and oversee or conduct clinical trials, often involving patients in residential settings—much like hospitals and health care facilities. These entities also assume responsibility for overseeing clinical trials on behalf of health care facilities that often lack necessary resources and expertise to manage the potential interference concerns of the Commission due to the use of new RF systems. Their clinical trials assess devices for patient

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9 21 C.F.R. § 812.3(o).

10 *See ERS Order* at ¶ 33.

11 *See* ClinicalTrials.gov, A Service of the U.S. National Institutes of Health, *available at* http://www.clinicaltrials.gov/. Medical device trials typically involve less than 1,000 subjects.

12 *Id.*

13 *Id.*

compatibility and use as well as operational, interference, and RF immunity performance in real world situations. Many medical devices studied in clinical trials are implanted at medical facilities but are eventually used by participating patients outside such facilities.

By limiting eligibility for medical testing licenses to health care facilities that sponsor or conduct clinical trials, the Commission's new experimental licensing regime does not align with FDA regulations that allow a variety of entities to sponsor or conduct clinical trial testing and creates regulatory uncertainty between the two regimes.

B. The Commission's New Experimental Licensing Framework Does Not Meet the Needs of the Medical Community and Threatens Medical Device Innovation

Other than the Mayo Clinic, none of the entities described above that also engage in clinical trial testing are eligible for the medical testing license under the Commission's new rules. Indeed, the new rules promulgated in the Commission's *ERS Order* do not meet the development and testing needs of a significant portion of the medical community and threaten to slow the pace of innovation.

The *ERS Order* creates three new types of ERS licenses: the program license, the medical testing license, and the compliance testing license.[14] Under the Commission's program license, qualified institutions are permitted to conduct an ongoing program of research and experimentation under a single experimental authorization at a geographic location under the licensee's control for a five year period on a non-interference basis.[15] But, the program license encompasses only basic research and experimentation—it does not cover clinical trials.[16]

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[14] *ERS Order* at ¶ 1. The *ERS Order* also consolidates rules for broadcasting experiments into a new subpart within Part 5.

[15] *Id.* at ¶ 34.

[16] *Id.* at ¶ 33. The Commission notes that a manufacturer of medical devices would be able to continue its product testing for clinical trials under its program license at a designated

Recognizing that the program license framework will "limit the ability of entities doing medical research to conduct clinical trials," the Commission established the medical testing license to "meet specific needs of the medical community for clinical trials."[17] However, the *ERS Order* restricts eligibility for medical testing licenses to hospitals and health care institutions, thereby excluding a variety of entities that sponsor or conduct clinical trials pursuant to FDA regulations.[18] As such, the Commission's new experimental licensing framework significantly limits the ability of a variety of sponsors and sponsor-investigators to engage in clinical trial testing. As the *ERS Order* recognizes, clinical trial testing is "necessary to ensure critical functions for many medical devices—such as remote monitoring, device tolerance to potential interference sources, and patient ability to use devices without the benefit of assistance."[19] Accordingly, the new rules hamper the medical community's ability to complete product testing expeditiously and to bring new, innovative devices to consumers.

In addition, by limiting the ability of entities doing medical device research to conduct clinical trials, the new rules arbitrarily impose additional costs and regulatory burdens on sponsors and sponsor-investigators that do not meet the Commission's definition of a "health care facility." Such a licensing regime unnecessarily burdens innovation to the harm of consumers, and ultimately undermines the very purpose of the medical testing license.

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innovation zone without having to apply for a separate product development trial license. *Id.* at fn. 212. While it is true that some hospitals will have RF engineering capabilities, they would be the exception, not the rule. Manufacturers would be limited by the number of health care facilities that request designation as an innovation zone for such testing. Moreover, innovation zones constitute defined geographic areas. As explained above, manufacturers require flexibility to conduct clinical trials in residential settings, potentially across multiple geographic regions. Finally, program licensees operating in an innovation zone still are subject to additional regulatory requirements not imposed on medical testing licensees. *Id.* at ¶ 95.

17 *Id.* at ¶¶ 104, 111.

18 *Id.* at ¶ 112.

19 *Id.* at ¶ 117.

C. The Commission Offers No Compelling Reason to Limit Eligibility for Medical Testing Licenses to Health Care Facilities

The Commission offers no justification for excluding sponsors and sponsor-investigators that are not "health care facilities" from benefitting from medical testing licenses. FDA-defined sponsors and sponsor-investigators are engaged in the health care field and have sufficient resources and expertise to oversee the RF aspects of clinical trial tests conducted under a medical testing license. As explained above, the public interest would be served by allowing these entities to benefit from the flexibility offered by medical testing licenses.

In addition, there is little risk of interference to licensed services from clinical trials conducted by manufacturers. Medical testing licenses will be used primarily for clinical trials, not basic medical research. As the Commission recognized, this means that "the basic RF experimentation for the medical device will have already been completed and the device will already have received FDA IDE approval for such testing"—reducing the likelihood of interference.[20] Moreover, as Medtronic previously demonstrated, and as the Commission agreed, clinical devices designed for use under the MedRadio Services rules of Part 95 and those that would operate under Part 15 pose little risk of interference.[21] Such devices operate at very low powers, meaning the likelihood of interference is remote.

Ultimately, medical testing licensees are responsible for ensuring that harmful interference is not caused to authorized spectrum users.[22] Sponsors and sponsor-investigators that are not "health care facilities" do not pose a unique risk of interference and, like health care facilities, should be eligible to receive medical testing licenses.

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20 *Id.*

21 Medtronic Comments at 7.

22 *ERS Order* at ¶ 116.

III. THE COMMISSION SHOULD CLARIFY THAT COST REIMBURSEMENT FOR CLINICAL TRIALS DOES NOT CONSTITUTE IMPERMISSIBLE "MARKETING" UNDER SECTIONS 2.803 AND 2.805

Medtronic applauds the Commission for broadening opportunities for market trials and clarifying when operation or marketing of radio frequency devices is permitted prior to equipment certification. However, as requested in its opening comments, Medtronic urges the Commission to clarify that cost reimbursement for clinical trials, as permitted under FDA rules, does not constitute impermissible "marketing" under Sections 2.803 and 2.805. The requested clarification will simplify manufacturers' compliance with the two relevant regulatory regimes without undermining the purpose of the Commission's marketing rules. Moreover, the requested clarification encourages medical device research and development.

Section 2.805 permits the operation of RF devices prior to equipment authorization in limited circumstances. Specifically, operation prior to equipment authorization is permitted under the authority of an experimental radio service authorization issued under Part 5 of the Commission's rules.[23] However, except in limited circumstances, RF devices operated pursuant to this exception may not be marketed.[24] Marketing includes the "sale or lease, or offering for sale or lease, including advertising for sale or lease, or importation, shipment, or distribution for the purpose of selling or leasing or offering for sale or lease."[25]

Under Section 2.803, limited marketing of unapproved devices is permitted for products that could be authorized under the Commission's rules.[26] An RF device may be advertised or displayed (*e.g.*, at a trade show or exhibition) if accompanied by conspicuous notice containing

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23 47 C.F.R. § 2.805(b).

24 47 C.F.R. § 2.803.

25 *Id.*

26 47 C.F.R. § 2.803(c)(2).

the language specified in Section 2.803(c)(2)(iii).[27] Evaluation kits, as defined in Section 2.803(c)(2)(iv), may be sold to product developers, software developers, and system integrators.[28] Pursuant to Section 2.803(c)(2)(ii), RF devices that are in the conceptual, developmental, design, or pre-production stage may be offered for sale solely to business, commercial, industrial, scientific, or medical users if the prospective buyer is advised in writing that the equipment is subject to Commission rules and the equipment will comply with such rules before delivery to the buyer or to centers of distribution.[29] The Commission's rules also permit manufacturers and prospective (non-end user) customers to enter into conditional sales contracts under Section 2.803(c)(2)(i).[30]

The FDA relies upon clinical trials to evaluate devices that have not yet been approved by the FDA as medical devices. As Medtronic previously explained, although manufacturers are not permitted by the FDA to profit from clinical trials, they are allowed to recover certain costs associated with the trials.[31] Specifically, the FDA's Investigational Device Exemption ("IDE") regulations allow clinical trial sponsors to charge for an investigational device so long as the charge does not exceed an amount necessary to recover the costs of manufacture, research, development, and handling of the investigational device.[32] The FDA generally allows sponsors

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27 47 C.F.R. § 2.803(c)(2)(iii).

28 47 C.F.R. § 2.803(c)(2)(iv).

29 47 C.F.R. § 2.803(c)(2)(ii).

30 47 C.F.R. § 2.803(c)(2)(i).

31 Medtronic Comments at 6.

32 *See* FDA Information Sheet, "Charging for Investigational Products," *available at* http://www.fda.gov/RegulatoryInformation/Guidances/ucm126427.htm ("FDA Information Sheet"). *See also*, 21 C.F.R. §§ 812.7(b), 812.20(b)(8).

to charge investigators for investigational devices, and this cost usually is passed on to subjects of the clinical trials.[33]

The Commission should clarify that cost recovery for devices used in clinical trials, as permitted by the FDA, does not constitute impermissible "marketing" under Sections 2.803 and 2.805. The public interest benefits of the requested clarification are clear. First, the purposes of the FDA's cost recovery mechanism align with the Commission's marketing restrictions. The FDA rules make clear that device manufacturers cannot profit from clinical trials—they only may recover certain costs associated with manufacture, research, development, and handling of devices used in clinical trials. Second, by alleviating some of the cost burdens on manufacturers, the FDA's cost recovery mechanism encourages medical device research and development that ultimately benefits consumers. Third, the requested clarification aligns Commission and FDA regulatory regimes and simplifies manufacturers' compliance. Otherwise, the Commission's regulations would make the FDA rules meaningless in this context. Medtronic therefore requests that the Commission clarify in its Memorandum Opinion and Order addressing this Petition that cost recovery for devices used in clinical trials as permitted by the FDA does not constitute impermissible "marketing" under Sections 2.803 and 2.805.

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[33] *See* FDA Information Sheet.

IV. CONCLUSION

Medtronic respectfully requests that the Commission reconsider the foregoing issues as requested above.

Respectfully submitted,

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May 29, 2013